

**THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ALABAMA
SOUTHERN DIVISION**

UNITED STATES OF AMERICA, et al.)
ex rel. BROOKS WALLACE,)
ROBERT FARLEY, and)
MANUEL FUENTES,)

Plaintiffs,

v.

EXACTECH, INC.,

Defendant.

CIVIL ACTION NUMBER
2:18-CV-01010-LSC

Opposed

Oral Argument Requested

EXACTECH, INC.’S MOTION FOR SUMMARY JUDGMENT

Pursuant to Rule 56 of the Federal Rules of Civil Procedure, Defendant Exactech, Inc. (“Exactech”) respectfully requests that the Court grant summary judgment in its favor and against Relators with respect to all causes of action asserted by Relators in the Amended Complaint. There are no genuine issues of material fact and judgment proper against Relators on all counts as a matter of law.

As demonstrated in the accompanying Memorandum of Law in Support of Exactech, Inc.’s Motion for Summary Judgment, the undisputed material facts do not support Relators allegations that Exactech violated the False Claims Act by selling an allegedly defective product—the Optetrak Finned Tibial Tray—and conspiring with a physician to cover-up the defective design of the Device. The

undisputed material facts also disprove Relators' further allegations that Exactech offered illegal remuneration to physicians to buy their silence.

Despite Relators' allegations that the Optetrak Finned Tibial Tray prematurely loosens from the tibia at an exceptionally high rate of 30–35%, the undisputed material facts show that the true percentage of revision surgeries due to tibial loosening is less than 1%. Exactech's data and peer-reviewed published studies prove that it has outperformed its market competitors. That's why the device is still on the market, and, to this day, continues to be manufactured and sold. It's also why, in the intervening three years since Relators filed their initial complaint, the FDA has taken no action to recall the device or withdraw its clearance. Because the undisputed material facts show that the Optetrak Finned Tibial Tray is not defective, there is no legal basis to conclude that Exactech caused the submission of false claims or that using the Optetrak Finned Tibial Tray in government-insured patients violates the False Claims Act. Nor is there a legal basis to conclude that Exactech knowingly or willfully induced physicians to suppress their concerns about a design defect by offering them consulting agreements, in violation of the Anti-Kickback Statute.

For all of the foregoing reasons, and for those stated in Exactech's Memorandum of Law, Exactech respectfully requests that the Court grant summary judgment in its favor and against Relators on all counts.

Respectfully submitted this 4th day of April, 2022.

HOGAN LOVELLS US LLP

/s/ Cory Wroblewski

Thomas Beimers (pro hac vice)
thomas.beimers@hoganlovells.com
80 South Eighth Street, Suite 1225
Minneapolis, MN 55402
Telephone: (612) 402-3000
FAX: (612) 402 3001

Jessica Black Livingston (pro hac vice)
jessica.livingston@hoganlovells.com
Cory Wroblewski (pro hac vice)
cory.wroblewski@hoganlovells.com
1601 Wewatta Street, Suite 900
Denver, Colorado 80202
Telephone: (303) 899-7300
FAX: (303) 899-7333

With permission:

/s/ Brandon K. Essig

Harlan I. Prater, IV
hprater@lightfootlaw.com
Brandon K. Essig
bessig@lightfootlaw.com
Amie A. Vague
avague@lightfootlaw.com
Lightfoot, Franklin & White LLC
The Clark Building
400 20th Street North
Birmingham, AL 35203
Telephone: (205) 581-0700

Attorneys for Defendant Exactech, Inc.

CERTIFICATE OF SERVICE

I hereby certify that on this 4th day of April, 2022, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system, which will send notice of such filing to all attorneys of record.

/s/ Cory Wroblewski

Cory Wroblewski